

negative. He later became HBeAg negative and HBeAb positive, but with an ALT level higher than before the treatment.

B. Effects of Germination Activated Ganoderma Spores on ASC (asymptomatic carriers) and CHB (chronic hepatitis B)

The therapeutic effects of ganoderma spores on ASC and CHB patients were similar and statistically insignificant.

C. Treatment Courses on Therapeutic Effects of Germination Activated Ganoderma Spores

As shown in Table 22, the therapeutic effects after two courses of treatment with ganoderma spores are better than one course of treatment with ganoderma spores. As indicated above, the 1st treatment course was continued for 45 days. After discontinued for 15 days later, the treatment was resumed (2nd treatment course) for additional 45 days.

TABLE 22

Treatment Courses on Therapeutic Effects of Ganoderma Spores

| | Case Number | Negative HBeAg | Positive HBeAb | Negative HBV DNA |
|----------------------------------|-------------|----------------|----------------|------------------|
| 1 st treatment course | 7 | 1 | 1 | 1 |
| 2 nd treatment course | 7 | 1 | 4 | 4 |

D. Observations for Adverse Effects After Treatment with Germination Activated Ganoderma Spores

All 14 patients completed the entire treatment program. Non has shown any fever or skin irritations. All patients maintained normal appetite and sleep pattern. The results of these studies indicate that the germination activated sporoderm-broken ganoderma spores were clinically safe with no apparent adverse effects on patients.

Clinical Example 2

Clinical Observations

The following are individual observations on patents treated with sporoderm-broken ganoderma spores.

1. Patient N: male, age 36.

Diagnosis: liver hepatitis B carrier; mother died of liver cancer "a few years ago". Patient N was given high dose of sporoderm-broken ganoderma spores between March, 1999 and September, 1999. In September, patient N's fatty liver and gall bladder polyps disappeared. Also, his HBV DNA was greatly reduced.

| Date | Observation | Change |
|----------------|------------------------------------|-------------------------|
| March 1999 | Fatty liver Gall bladder polyps | |
| July 1999 | HBV DNA 3490 pg/ml | |
| September 1999 | HBV DNA 620 pg/ml Normal liver | Reduced to normal range |

2. Patient L: male, age 62.

Patient L was diagnosed with hepatoma (tumor size: 5.1×6.6×7.7 cm) with tumor located at the portal vein region of the liver. He started high dose of ganoderma spores treatment in May, 1999. In August, 1999, X-ray data confirmed that his tumor reduced to 3.5×3.4×3 cm. Between May and August, 1999, ganoderma spores were the only medicine that patient L had taken.

| Date | Observation | Change |
|-------------|---|--------|
| May 1999 | Confirmed liver cancer Tumor size 5.1 × 6.6 × 7.7 cm | |
| August 1999 | Other satellite tumors present Tumor size 3.5 × 3.4 × 3 cm | |

3. Patient C: Male, age 44.

Patient C was diagnosed with hepatitis B and early liver cirrhosis, and was admitted to hospital since 1997. Patient

| Date | Observation | Change |
|------------|---|-------------------|
| March 1999 | Hepatitis B and jaundice | Started treatment |
| Present | Liver hepatitis B and only cirrhosis HBV DNA 5 pg/ml | |

4. Patient L-1: male, age 67

Patient L-1 was diagnosed with poor glucose control for 10 years even after injection of insulin. In March, 1999, Patient L-1's hemoglobin Alc (HbAlc) was 16.4%. Patient L-1 started high dose of germination activated sporoderm-broken ganoderma spores treatment in March, 1999. In August, 1999, his HbAlc reduced to 10%, which was within the range of moderate glucose control.

| Date | Observation | Change |
|-------------|--------------|--------|
| March 1999 | Hb Alc 16.4% | |
| August 1999 | Hb Alc 10% | |

Treatment started in March. Result: moderate glucose control.

While the invention has been described by way of examples and in terms of the preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments. On the contrary, it is intended to cover various modifications as would be apparent to those skilled in the art. Therefore, the scope of the appended claims should be accorded the broadest interpretation so as to encompass all such modification.

What is claimed is:

1. A pharmaceutical preparation comprising

activation sporoderm-broken ganoderma spores and optionally a pharmaceutically acceptable carrier; wherein said activated sporoderm-broken ganoderma spores are prepared by:

soaking ganoderma spores in a solution which is selected from the group consisting of water, saline, and a nutritional solution to cause the spores to germinate; placing said germination-treated ganoderma spores in a culture box at a relative humidity of 65–98% and temperature of 18–48° C. to cause the germinated ganoderma spores to activate; and treating the germination activated ganoderma spores to break the pores to produce activated sporoderm-broken ganoderma spores.

2. The pharmaceutical preparation according to claim 1, wherein said ganoderma spores are soaked in the solution for 30 minutes to 8 hours at no more than 50° C.

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3. The pharmaceutical preparation according to claim 1, wherein said nutritional solution is at least one selected from the group consisting of coconut juice, malt extract, ganoderma sporocarp extract, ganoderma capillitia extract, culture solution containing biotin, and culture solution containing monobasic potassium phosphate and magnesium sulfate. 5

4. The pharmaceutical preparation according to claim 2, wherein said ganoderma spores are soaked in the solution for 2 to 4 hours.

5. The pharmaceutical preparation according to claim 2, 10 wherein said ganoderma spores are soaked in the solution at 20 to 43° C.

6. The pharmaceutical preparation according to claim 1, wherein said solution is 0.1–5 times the weight of said spores.

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7. The pharmaceutical preparation according to claim 1, wherein the spores are broken by treating the germination activated ganoderma spores with an enzyme with a cell wall dissolving property.

8. The pharmaceutical preparation according to claim 7, wherein enzyme is chitinase or cellulase.

9. The pharmaceutical preparation according to claim 1, wherein the spores are broken by treating the germination activated ganoderma spores with a mechanical force.

10. The pharmaceutical preparation according to claim 9, wherein said mechanical force is at least one selected from the group consisting of a micronization, roll pressing, grinding, ultrasound, and super high pressure microstream treatment.

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